

Docket Number: 10030304-1
Serial Number: 10/668,749

REMARKS

Claim Objections

The claims were objected to for various informalities. Applicant believes it has responded to the informalities by amended the claim numbering of former claim 22, and by the amendments to claim 18. Applicant respectfully requests that the objections be withdrawn.

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Claim Rejections under 35 U.S.C. §101

Claims 1-21 have been rejected under 35 USC 101 as allegedly being directed to non-statutory subject matter. Applicant respectfully traverses. Nevertheless to facilitate early allowance of the claims, independent claims 1 and 15 have been amended to recite further useful, concrete, and tangible results. Specifically, claims 1 and 15, as amended, recite "to aid in a determination of at least one of the following: phosphorylation state of the target polynucleotides, length diversity among polynucleotides present in a sample, chemical integrity of the target polynucleotides, and a ratio of target polynucleotides to non-target polynucleotides in the sample." This subject matter is an outcome of the claimed methods and systems, and recites a concrete, tangible, and useful result of the claimed methods and systems.

Further, the amendments add no new matter. For example, support for the claim amendments can be found in the originally-filed specification at least at page 8, lines 3-7 and FIG. 1. For at least this reason, Applicant respectfully requests that the rejection of the claims be withdrawn.

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Claim Rejections under 35 USC §112, Second Paragraph

Claims 1-14 have been rejected under 35 U.S.C. § 112, second paragraph, as being allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. Applicant has amended independent claim 1 and dependent claim 5 herein. In that the Examiner's objections are believed to have been overcome, Applicant respectfully requests that the rejection of these claims under 35 U.S.C. § 112, second paragraph, be withdrawn.

Applicant wishes to clarify that the foregoing amendments have been made for purposes of better defining the invention in response to the rejections made under 35 U.S.C. § 112, and not in response to the rejections made based on prior art. Indeed, Applicant submits that no substantive limitations have been added to the claims. Therefore, no prosecution history estoppel arises from these amendments. *Black & Decker, Inc. v. Hoover Svc. Ctr.*, 886 F.2d 1285, 1294 n. 13 (Fed. Cir. 1989); *Andrew Corp. v. Gabriel Elecs., Inc.*, 847 F.2d 819 (Fed. Cir. 1988); *Hi-Life Prods. Inc. v. Am. Nat'l Water-Mattress Corp.*, 842 F.2d 323, 325 (Fed. Cir. 1988); *Mannesmann Demag Corp. v. Eng'd Metal Prods. Co., Inc.*, 793 F.2d 1279, 1284-1285 (Fed. Cir. 1986); *Moeller v. Ionetics, Inc.*, 794 F.2d 653 (Fed. Cir. 1986).

Claim Rejections under 35 USC §112, First Paragraph

Claims 1-21 have been rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the enablement requirement. Applicant respectfully traverses.

Nevertheless to advance prosecution and facilitate early allowance of the claims, Applicant has amended the claims to recite features relating to performing nanopore analysis on polypeptide data, which the Office admits is enabled by the specification. *See Office Action* at page 5. In that

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the Examiner's objections are believed to have been overcome, Applicant respectfully requests that the rejection of these claims under 35 U.S.C. § 112, first paragraph, be withdrawn.

Claim Rejections under 35 USC §102

(a) Claims 1, 2, 10, 12, 15, 16, 20, and 21 have been rejected under 35 U.S.C. § 102(a) as being allegedly anticipated by *Haussler et al.* ("*Haussler*," 30 May 2002, International Publication Date). Applicant respectfully traverses this rejection.

It is axiomatic that "[a]nticipation requires the disclosure in a single prior art reference of each element of the claim under consideration." *W. L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1554, 220 USPQ 303, 313 (Fed. Cir. 1983). Therefore, every claimed feature of the claimed invention must be represented in the applied reference to constitute a proper rejection under 35 U.S.C. § 102.

In the present case, not every feature of the claimed invention is represented in the *Haussler* reference. Specifically, independent claims 1 and 15 have been amended to recite the features of analyzing a distribution of polynucleotide data points in the distribution pattern "to aid in a determination of at least one of the following: phosphorylation state of the target polynucleotides, length diversity among polynucleotides present in a sample, chemical integrity of the target polynucleotides, and a ratio of target polynucleotides to non-target polynucleotides in the sample." Instead, *Haussler* discloses "[i]f the observed signature matches the reference signature, the measured sample is determined to include the analyte duplex nucleic acid having the reference signature, i.e., the presence of the analyte duplex nucleic acid in the sample being assayed is positively identified." *Haussler* at page 15, lines 18-21. Because *Haussler* merely

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discloses identifying one particular nucleic acid in a sample and not any of the features recited above, *Haussler* does not anticipate or render obvious the independent claims 1 and 15.

In addition, Applicant reserves the right to allege an invention date prior to the publication date of *Haussler* and does not admit that *Haussler* is prior art under 35 U.S.C. 102(a).

Because independent claims 1 and 15 are allowable over *Haussler*, dependent 2, 10, 12, 16, 20, and 21 are allowable as a matter of law for at least the reason that the dependent claims 2, 10, 12, 16, 20, and 21 contain all elements of their respective base claim. *See, e.g., In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988).

Due to the shortcomings of the *Haussler* reference described in the foregoing, Applicant respectfully asserts that *Haussler* does not anticipate Applicant's claims. Therefore, Applicant respectfully requests that the rejection of these claims be withdrawn.

(b) Claims 1, 2, 10, 12, 15, 16, 20, and 21 have been rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by *Meller et al.* ("*Meller*," PNAS (200) Vol. 97, No. 3, pages 1079-1084). Applicant respectfully traverses this rejection.

Not every feature of the claimed invention is represented in the *Meller* reference. Specifically, independent claims 1 and 15 have been amended to recite the features of analyzing a distribution of polynucleotide data points in the distribution pattern "to aid in a determination of at least one of the following: phosphorylation state of the target polynucleotides, length diversity among polynucleotides present in a sample, chemical integrity of the target polynucleotides, and a ratio of target polynucleotides to non-target polynucleotides in the sample." Instead, *Meller* discloses "the distribution as indicative of polymers of the same

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length.” *Office Action* at page 8, 5th paragraph (emphasis added). Because *Meller* merely discloses identifying polymers of the same length and not any of the features recited above, *Meller* does not anticipate or render obvious the independent claims 1 and 15.

Because independent claims 1 and 15 are allowable over *Meller*, dependent 2, 10, 12, 16, 20, and 21 are allowable as a matter of law for at least the reason that the dependent claims 2, 10, 12, 16, 20, and 21 contain all elements of their respective base claim. *See, e.g., In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988).

Due to the shortcomings of the *Meller* reference described in the foregoing, Applicant respectfully asserts that *Meller* does not anticipate Applicant’s claims. Therefore, Applicant respectfully requests that the rejection of these claims be withdrawn.

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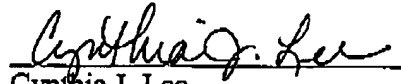
CONCLUSION

Applicant respectfully requests that all outstanding objections and rejections be withdrawn and that this application and all presently pending claims be allowed to issue. If the Examiner has any questions or comments regarding Applicant's response, the Examiner is encouraged to telephone Applicant's undersigned counsel.

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Respectfully submitted,



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